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CuraGen Corporation (ticker: CRGN, exchange: NASDAQ) News Release - 4-Mar-2003

CuraGen Receives FDA Approval to Initiate Clinical Trials

NEW HAVEN, Conn., Mar. 4 - (PRNewswire-FirstCall via GENWIRE) --CuraGen Corporation (Nasdaq: CRGN), a genomics-based pharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has approved its Investigational New Drug (IND) application to initiate clinical trials for CGS3135, a potential protein therapeutic being investigated as a treatment for oral mucositis. Oral mucositis is a side effect of chemotherapy and radiotherapy that results in the degradation of mucosal tissue that can range from redness and irritation to severe ulcerations of the mouth and throat. CuraGen now plans to proceed with a multi-center Phase I clinical trial to evaluate safety and pharmacokinetics in patients with cancer who are at risk for mucositis following chemotherapy.

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Potential Oral Mucositis Treatment Marks Successful Transition into Drug Development

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Mucositis is a debilitating complication of cancer chemotherapy or radiotherapy that affects the mucosal tissue, which acts as a protective lining within the digestive track, including the mouth and throat. Symptoms range from pain and discomfort to severe ulcerations that limit a patient's ability to ingest nutrients. Mucositis can result in a suppressed immune system that can reduce a patient's ability to tolerate further cancer therapy. Delayed treatment can lessen the effectiveness of the chemotherapy or radiotherapy, adversely impacting the value of the patient's overall treatment regimen.

"CGS3135 is a novel protein discovered through the application of CuraGen's functional genomic technologies. In preclinical studies, this potential protein therapeutic reduced tissue inflammation and degeneration, and minimized the severity and extent of mucosal tissue damage. Mucositis is a significant unmet medical need, and we are pleased to have the opportunity to advance this promising molecule into human clinical trials," stated Timothy R. Shannon, M.D., Senior Vice President of R&D and Chief Medical Officer of CuraGen Corporation.

"Through the funding of this IRG, CuraGen has become one of the first academics companies to successfully transition from a target discovery company into a genomics-based pharmaceutical company. This molecule represents the first of many promising candidates that we believe will emerge from our portfolio of discovery and preclinical stage projects. We are pleased with the progress of this potential therapeutic and look forward to additional future successes," stated Jonathan M. Rothberg, Ph.D., Founder, Chairman, and CEO of CuraGen Corporation.

About CuraGen

CuraGen Corporation (NASDAQ:CRGN) is a genomics-based pharmaceutical company. CuraGen's integrated functional genomic technologies and Internet-based bioinformatic systems are designed to generate comprehensive information about genes, human genetic variations, gene expression, protein interactions, protein pathways, and potential drugs that affect these pathways. The Company is applying its undrugged genomic technologies, informatics, and validation technologies to develop protein, antibody, and small molecule therapeutics to treat obesity and diabetes, cancer, inflammatory diseases, and central nervous system (CNS) disorders. CuraGen is headquartered in New Haven, CT and additional information is available at www.curagen.com.

This press release may contain forward-looking statements, including statements about CRGN's commitment and ability to reduce tissue inflammation and degeneration, and minimize the severity and extent of musculoskeletal damage in preclinical studies, as well as representing the first of many promising candidates that we believe will emerge from our portfolio of discovery and preclinical stage projects. Such statements are based on management's current expectations and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. CuraGen cautions investors that there can be no assurance that actual results or business conditions will not differ materially from those projected or suggested in such forward-looking statements as a result of various factors, including, but not limited to, the following: CuraGen's expectation that it will incur operating losses in the near future; the early stage of development of CuraGen's products and technology; uncertainties related to preclinical and clinical testing and trials; uncertain and adverse results relating to CuraGen's ability to obtain regulatory approval for its products in development; uncertainties surrounding the availability of additional funding; CuraGen's reliance on research collaborations and strategic alliances; the actions of competitors; the development of competing technologies; CuraGen's ability to protect its patents and proprietary rights; patent infringement actions; and uncertainties relating to commercialization, if any. Please refer to our Annual Report on Form 10-K for the third year ended December 31, 2001 for a description of these risks. We disclaim any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.

SOURCE: CuraGen Corporation

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